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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/851,670 | 05/08/2001 | Christoph Reinhard | PP-01699.002/200130.520 | 3261 |

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EXAMINER

SCHMIDT, MARY M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1635

DATE MAILED: 02/04/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,670

Applicant(s)

REINHARD ET AL.

Examiner

Mary M. Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-8-2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,12,13,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,17 and 18 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: The attached notice of references cited, PTO-892, is a corrected copy of the notice of references cited mailed with the Office action on 5/8/2002.

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DETAILED ACTION

1. Please note that a new copy of the PTO-892, notice of references cited, from the previous Official action mailed 5/8/02 is included herein. The references in the previous PTO-892 had numerous typographical errors, and omissions of relevant bibliographic data.

Claim Objections

2. Claims 5, 12, 13, 17 and 18 are objected for the language "from the group consisting of SEQ ID NO:2-6 and 12-19" since the claim as currently written fails to properly claim the SEQ ID NOS. in the alternative as required by MPEP 2173.05(h). The claim would more clearly recite the Markush group claimed if re-written to state "from the group consisting of SEQ ID NO:2, 3, 4, 5, 6, 12, 13, 14, 15, 16, 17, 18 and 19."

Claim 18 would be more clearly stated as "A recombinant vector comprising the isolated polynucleotide of claim 17."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 5, line 1, lacks antecedent basis for "said antisense".

Claims 17 and 18 (for its dependency on claim 17) are indefinite since the meets and bounds of the claimed polynucleotide is unclear. It is not clearly defined in the specification as filed whether the 8-35 base sequence comprising a sequence from the group of SEQ ID NOS:2-6 and 12-19 also comprising a transcriptional initiation region refers to the binding of the claimed SEQ ID NOS. to a transcriptional initiation region of the target gene, or whether the antisense sequences are linked chemically to a transcription initiation region for transcription of the sequences in a vector such as that of claim 18.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 is drawn to an isolated polynucleotide with a sequence comprising a transcriptional initiation region and a sequence encoding an antisense oligonucleotide at least 8 nucleotides or nucleotide analogues and not longer than 35 nucleotides in length comprising a

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sequence selected from the group consisting of SEQ ID NOS:2-6 and 12-19. Claim 18 depends from claim 17 and is drawn to a vector composition comprising polynucleotide having a DNA with a sequence of claim 17.

The specification as filed teaches the sequences of SEQ ID NOS:2-6 and 12-19 on pages 6-7 and states in lines 14-17 that “[t]he invention includes within its scope any oligonucleotide of about 8 to about 35 nucleotides in length... wherein the oligonucleotide hybridizes to a Akt3 polynucleotide, including DNA or mRNA.” The specification as filed does not further show that the individual antisense bind to the transcription initiation region, nor does the description of vectors on pages 27-28 discuss use of transcription initiation regions specifically in relation to expression of the disclosed antisense SEQ ID NOS.

In view of the 35 U.S.C. 112, 2nd paragraph, rejection above, one of skill in the art would not have recognized that applicant was in possession of the breadth of claimed oligonucleotide compositions since the specification as filed did not teach specific transcriptional initiation regions for use in conjugation with the recited SEQ ID NOS. for antisense expression, nor did the specification as filed indicate the all of SEQ ID NOS. 2-6 and 12-19 bind to the transcription initiation region of Akt3. SEQ ID NOS: 4, 12 and 18 have “CAT” sequences within them that could potentially be binding sites for the “ATG” start codon of the Akt3 gene. However, it is not clear which, if any of them, actually does bind to the Akt3 gene, since the start codon of the Akt3 sequence in Figure 6 (SEQ ID NO:1) has not been described in the specification as filed. Therefore, applicant is not considered in possession of a representative number of species of the

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compositions of claims 17 and 18 in view of the lack of written description support in the specification as filed for the relationship between "transcriptional initiation region" and SEQ ID NOS.2-6 and 12-19.

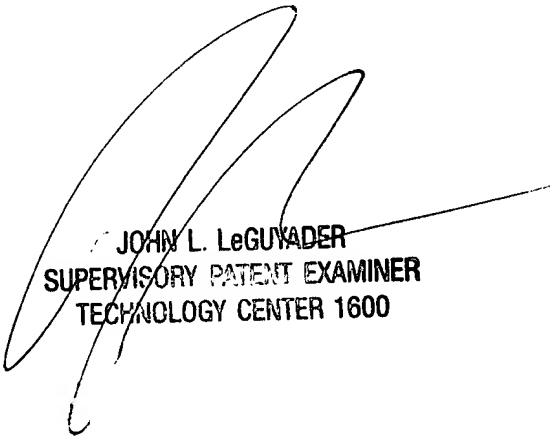
7. Claims 5, 12, 13, 17 and 18 are free of the prior art since the prior art did not teach nor fairly suggest the antisense compounds of instant SEQ ID NOS. 2-6 and 12-19, vectors encoding said sequences, nor methods of using said sequences to inhibit the Atk3 gene in cells in culture, *in vitro*.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
January 27, 2003



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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